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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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[REDACTED] EXAMINER

LAZAR WESLEY, ELIANE M

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1646

DATE MAILED: 07/30/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/254,760

Applicant(s)

Kato

Examiner

Eliane Lazar-Wesley

Art Unit

1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Jun 24, 2002
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 5-18 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 5-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1 Notice of References Cited PTO-892 4 Interview Summary PTO 413 Paper No. _____
2 Notice of Draftsperson's Patent Drawing Review PTO-948 5 Notice of Informal Patent Application PTO 152

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DETAILED ACTION

1. The amendment filed January 16, 2002, has been entered.

The substitute CRF filed June 24, 2002, has been received and is in compliance.

2. Applicant's election without traverse of Group IX directed to the polypeptide HP10368 and its corresponding amino-acid and nucleotide sequences of SEQ ID No:9, 18 and 27, in Paper No. 9 filed January 16, 2002 is acknowledged.

Claims 5-18 are under consideration.

Priority

This application claims priority to PCT/JP97/03239 filed September 12, 1997. The amino acid sequence of SEQ ID No:9 (HP10368) and the DNA sequences of SEQ ID No:18 and 27 have been disclosed in the parent Japanese application JP8/243060 filed September 13, 1996 (see page 92). The Japanese application JP8/243060 is present in the file, and while no translation was provided, the sequence at page 92 is labeled HP10368 and appears to be identical to SEQ ID No:9, 18 and 27.

Claim Rejections - 35 USC § 101

requirements of this title

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4. Claims 5-18 are rejected under 35 U.S.C. 101, because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The claims are to an isolated polypeptide having SEQ ID No:9, to polypeptides consisting of at least 5 amino acids of SEQ ID No:9, to DNA encoding the polypeptides, and to DNA encoding polymorphic variants of the polypeptide of SEQ ID No:9.

The present invention is based upon the discovery of a novel DNA sequence that encodes a polypeptide having a putative secretory signal sequence. The DNA has been isolated from human stomach cancer cDNA libraries (page 34). The protein, like the other proteins disclosed in the specification, is considered as putatively controlling the proliferation and differentiation of the cells (page 36). Applicants recite a long list of numerous potential uses (pages 36-62) on the basis that the protein has a putative secretory signal sequence. However, applicants do not provide a specific and substantial utility for the protein of the invention, and the DNA encoding it. While applicants disclose that the DNA is isolated from stomach cancer cDNA libraries, they do not show if the DNA is expressed in normal stomach cells, or in other normal or cancerous cells, or in embryonic cells for example, and what specific use the protein HP10368 or the DNA encoding it , has.

The specification merely identifies a naturally occurring nucleic acid which encodes a protein having a putative signal secretory sequence, and issues an invitation to the skilled artisan to determine how to use the invention. See 35 U.S.C. § 101, which states that "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may be patented."

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The Examiner's position is supported by the case law. In *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sup. Ct., 1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be useful because the compound produced thereby was potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility.

The instant claims are drawn to a protein which has undetermined function or biological significance. Until some actual and specific activity can be attributed to the protein identified in the specification as HP10368 protein or the polynucleotides encoding it, the claimed invention is incomplete.

A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentech, Inc. v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

"[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute a disclosure." The court further stated:

"[t]he claim elements requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge

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of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The claimed invention has no utility and the instant specification is not enabling because one cannot, following the guidance presented therein, use the claimed products and method without first making a substantial inventive contribution.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 5-18 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, even if the protein of the invention would have utility, the claims are to proteins fragments of at least 5 amino acids of SEQ ID No:9, and to DNA having 90% identity with SEQ ID No:18 or 27, or to polymorphic variants. Claim 8 is to fragments of SEQ ID No:9, and one of skill in the art wouls not know what to use these fragments for. As for claims to DNA having 90%

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would allow to maintain a biological activity, as there is no indication about the essential motifs or sequences that would provide activity, if any.

Furthermore, claims 11 and 13 are rejected for lack written description, as there is no indication that applicants were in posession of such variants and how to define a functional variant, and because the specification does not teach that Applicants were in possession of the genus claimed.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Yu teaches a protein , huXAG1, of SEQ ID No:2, and the nucleic acid sequence of SEQ ID No:1 encoding it. Yu's protein of SEQ ID No:2 is 100% identical to the instant SEQ ID No:9 over its entire length. Yu's DNA is 99.7% identical to SEQ ID No:18, and 97.9% identical to SEQ ID No:27 (see sequence comparisons, attached). Claims 9, 10, 12 are not included in the rejection because Yu's DNAs are not identical to the claimed DNAs.

Yu also teaches a protein of SEQ ID No:6, huXAG3, which has fragments of more than 5 amino acids identical to fragments of the instant SEQ ID No:9 (see sequence comparison, attached).

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sive et al, Cell 58:171-180, 1989, teaches the nucleic acid encoding XAG-2. XAG-2 comprises fragments of more than 5 amino acids identical to fragments of the instant SEQ ID No:9. (see sequence comparison, attached).

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliane Lazar-Wesley, PhD, whose telephone number is (703) 305 4059. The examiner can normally be reached on Monday-Friday from 9:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308 4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding

JULY 24, 2002

ESW

Eliane Lazar-Wesley
YVONNE EYLER, PhD
Examiner
July 24, 2002